

REMARKS

Applicant's Attorney extends his appreciation to the Examiner for the brief telephone interview on December 4, 2002 wherein the status of claim 25 was clarified as being rejected under 35 USC §102. Applicant's Attorney believes that an additional telephone interview may be useful following the Examiner's consideration of this Amendment A, and accordingly respectfully requests that he be contacted to discuss the same at the Examiner's convenience.

In response to the September 12, 2002 Official Action, claims 16-18, 23, 25, 27 and 29-30 have been cancelled without prejudice, claims 1, 7, 14, 19, 21, 24 and 26 have been amended, and new claims 32-42 have been added, all in a sincere effort to place the application in condition for allowance. Reconsideration is respectfully requested.

Addressing the specific rejections of the Office Action in the order that they were presented, claim 19 was rejected as directed to non-statutory subject matter under 35 U.S.C. §119. Claim 19 has been amended to overcome the rejection. Namely, the outlet has been amended to be "configured for" connection to an aorta.

Claims 14 and 21-24 were rejected as indefinite under 35 U.S.C. §112. Claim 23 has been cancelled. Claims 14 and 21 have been amended to overcome the rejection. The structure recited in claim 14 has been further defined, and "a pumping cycle" has been introduced to overcome the lack of an antecedent basis in claim 21. It is believed that the amendment of claim 21 overcomes the indefiniteness rejections of claims 21-24. The Examiner indicated that the claims 23-24 would be allowable if re-written in independent form. Claim 23 has been cancelled without prejudice and re-written as new independent claim 35. Claim 24 has been amended to depend from claim 35.

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Claims 1-4, 10, 12-15, 19, 21, 22, 26, 28 and 31 were rejected as anticipated by U.S. Patent No. 4,133,616 to *Poirier* ("*Poirier*"); and claims 1, 2, 5, 8-11, 14, 15, 19-21, and 29-31 rejected as anticipated by U.S. Patent No. 5,222,980 to *Gealow* ("*Gealow*"). During the above noted telephone interview, it was indicated that claim 25 also stands rejected as anticipated by *Poirier* and/or *Gealow*.

A claim is anticipated under 35 U.S.C. § 102 only if a single prior art reference discloses, expressly or inherently, each and every element as set forth in the claim. *Verdegaal Bros. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the patent claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Every limitation must be shown. *Id.*

Independent claim 1 has been amended for clarification. With regards to amended claim 1 and claims 2-5, 8-10, 15 and 19-20 that depend from claim 1, it is submitted that neither *Gealow* nor *Poirier* disclose all the claim limitations, and therefore the claims are not anticipated. Claim 1 recites an elastic bladder with at least a portion of the interior surface area of the bladder being changeable between an expanded and contracted state. The claim has been amended to clarify that this change in area is between a first surface area and a substantially larger second surface area. This is an important aspect of the invention. The changing of the surface area of the bladder between contracted and expanded states is believed to reduce or prevent blood clots from forming on the surface of the bladder. See, e.g., specification, p. 5, lines 7-22. The elastic bladder with its changing surface area also tends to reduce flow stagnation, and promote smoother, less turbulent flow. See, e.g., specification, p. 14 lines 21 - p.

15, line 3. This is in contrast to conventional positive displacement pumps that can cause turbulent, disruptive flow patterns. Smooth, less turbulent flow is desirable for several reasons, including reduction of thrombosis.

Neither of *Gealow* nor *Poirier* disclose an elastic bladder that has an interior surface area capable of changing between a first surface area and a substantially greater second surface area as is recited in claim 1. When considering the disclosures of the *Gealow* and *Poirier* references (as well as other prior art references), two important distinctions must be appreciated. One, there is a difference between "flexible" and "elastic" bladders. The term "flexible" does not require that a bladder stretch significantly under operating conditions. An ordinary canvas sheet, for example, may be flexible, but is not elastic. Second, a bladder having a changeable *volume* does not require a changeable bladder *surface area*. It is submitted that whereas *Gealow* and *Poirier* disclose "flexible" diaphragms with changeable pumping chamber volumes, neither disclose expressly or inherently an *elastic* bladder having a changeable interior *surface area* that changes between a first surface area and a substantially greater second surface area as recited in claim 1.

Poirier states that the bladder 52 is flexible (col. 1, line 53), but does not say that it is elastic, or that it changes surface area during the pumping cycle. Further, the reference states that upon application of a driving pulse, "the bladder 52 will *collapse* ..." and that when "the diaphragm means 14 abuts the end of the housing 12 opposite the stop means 42, the bladder 52 cannot be further *collapsed* regardless of the force of the pulse emanating from the driver means 36." Col. 3, line 57 to col. 4, line 2. It is noteworthy that the term "collapsed" is used, which is appropriate to describe a bladder that is flexible but not elastic. The specification confirms that the bladder 52 shown in Fig. 2 operates by using a driving gas to *collapse* the bladder 52, and venting of the driving gas allowing the bladder 52 to

refill. See, *Poirier*, col. 3, line 57 - col. 4, line 23. No mention is made of a change of surface area of bladder 52 between a first surface area and a substantially greater second surface area.

Further, *Poirier* teaches that the inside surface of the bladder is flocked with fibers to promote formation of a biological layer on the interior surface. *Poirier*, col. 1, lines 30-33. Clearly such a biological layer would come loose, be damaged, or even destroyed should the interior surface area of the bladder be changeable. For example, should the interior surface area stretch, the biological layer could tear or come loose. A dislodged piece of the biological layer could interfere or block blood flow, causing catastrophic results. Accordingly, it is submitted that *Poirier* teaches away from the recitations of claim 1.

Gealow also teaches a diaphragm 28 that is flexible, but that does not have a changeable interior surface area as recited in claim 1. Indeed, *Gealow* teaches that the diaphragm 28 is "shape retaining," and therefore also teaches away from the claimed bladder that changes surface area. See, col. 7, lines 24-25. *Gealow's* drawings, Figs. 2 and 4, confirm that the surface area of the diaphragm 28 is substantially the same between its blood-filled state (diaphragm 28 in concave position against inner housing wall 14) and its blood-ejected state (broken line showing that the diaphragm in convex position spaced away from wall 14). The cross-sectional dimension of the bladder is substantially the same in the concave (filled) and convex (ejected) positions. There is no disclosure of elastic expanded/contracted inner surface area of the bladder.

Thus, the cited prior art references disclose traditional diaphragm type pumps that have *flexible* but not *elastic* diaphragms. Neither reference teaches elements recited by claim 1 such as an elastic bladder having an interior surface area that is changeable between a contracted state have a first surface area

and an expanded state having a substantially greater second surface area. Both references, in fact, teach away from the recitations of claim 1. Because neither *Poirier* nor *Gealow* disclose the structure of amended claim 1, claim 1 and all claims dependent on it cannot be anticipated by the references.

Claim 3 stands rejected as anticipated by *Poirier*. Claim 3 is allowable not only because it depends from amended claim 1, but also because it recites an additional element not disclosed by *Poirier*. Claim 3 recites a vacuum pump for changing the pressure of the fluid between the housing and the bladder. *Poirier* doesn't disclose a vacuum pump, but instead teaches use of a pneumatic driver means 36 that provides positive pressure to drive contraction of the pump diaphragm 14:

Upon generation of a *positive pressure pulse above the environmental pressure*, ... The pulse... *is of a magnitude greater than the arterial pressure* ... so that the bladder 52 will collapse and drive its contents into the conduit 56.

Col. 3, lines 49-60 (emphasis added). Because claim 3 includes an element not taught or suggested by *Poirier*, claim 3 is allowable over *Poirier*.

Dependent claim 7 is allowable. The cited references do not disclose a semi-solid unitary bladder and actuating fluid.

Independent claim 21 also stands rejected as anticipated by both *Poirier* and *Gealow*. Claim 21 is allowable for similar reasons as advanced relative to claim 1, namely that the cited references do not disclose an extensible bladder and means to expand and contract the interior surface area during the pumping cycle. Further, claim 21 as amended defines the pressure altering means as operable to maintain the pressure between a high pressure and a low pressure

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that is below atmospheric. As discussed above relative to claim 3, *Poirier* does not disclose this feature, and instead teaches a diaphragm that is in a "blood-filled" state when at a low pressure of about atmospheric and uses a high positive pressure to collapse the diaphragm to pump the blood. See, *Poirier*, col. 3, lines 49-60.

Similarly, *Gealow* teaches using a positive (greater than arterial) pressure to drive pumping. *Gealow* teaches forcing a driving fluid into the expansion chambers 32 to force the diaphragm 28 away from the housing wall 12 when the interior of the diaphragm 12 is exposed to arterial pressure. See, *Gealow*, col. 8, line 50 - col. 9, line 10. Accordingly, neither of *Poirier* nor *Gealow* disclose the claimed elements of amended claim 21, and the claim is therefore not anticipated.

Claim 22 stands rejected as anticipated by *Poirier*. Claim 22 depends from claim 21 and additionally recites driving the bladder between a high and a low pressure, with the *high* pressure being *at or below atmospheric pressure*. Claim 22 further recites the bladder *expanding* when the *low* pressure is applied and *contracting* when the *high* pressure is applied. *Poirier*, on the other hand, teaches allowing the diaphragm 14 to *expand* when exposed to atmospheric pressure, and to *contract* the diaphragm 14 with a *high pressure* that is *greater than atmospheric* and greater than the arterial pressure. *Poirier*, col. 3, lines 49-60. The reference further states: "In operation of the preferred embodiment herein described, the chamber 30 is at an environmental state when in maximum volume state." *Id.*, col. 5, lines 29-32. Because claim 22 depends from claim 21 and includes elements not present in *Poirier*, it is not anticipated and should be allowed.

Independent claim 26 stands rejected as anticipated by *Poirier*. Claim 26 has been amended to recite storing elastic energy in the bladder as the

bladder is expanded, and recoiling the bladder to release the stored energy, with said released elastic energy contributing to the contracting step. As discussed herein above, these method steps are not disclosed by *Poirier*, which instead teaches use of a positive pressure to drive contraction of the diaphragm. For this reason, amended claim 26 is not anticipated.

Claims 28-31 stand rejected as anticipated by *Poirier* and/or *Gealow*. Claims 29-30 have been cancelled. Claim 28 is allowable because it depends from amended claim 26. Claim 31 is not anticipated by the references for reasons discussed herein above. For example, claim 31 recites an extensible bladder, and expanding and contracting a majority of the surface area of the extensible bladder. The cited references do not disclose or suggest these features.

Claims 5-7, 11 and 20 have been rejected as obvious under 35 USC §103(a) over *Poirier*. Likewise, claims 6-7 have been rejected as obvious over 35 USC §103(a) over *Gealow*. In order to establish a *prima facie* case of obviousness under 35 USC §103, all of the limitations of the claims must be shown in the prior art reference (or references when combined). M.P.E.P. § 2142. Further, there must be a teaching or suggestion in the prior art references to motivate combining the references. It is submitted that a *prima facie* case has not been made because there are claim limitations that are not disclosed or suggested in any of the cited references.

It is respectfully submitted that claims 5-7, 11 and 20 are not obvious over *Poirier* and *Gealow* because claim 1 from which they depend includes features and limitations not disclosed by the references, specifically, an elastic bladder with a changeable interior surface area changeable between a first surface area and a substantially larger second surface area. Accordingly, a *prima facie* case of obviousness cannot be established. Further, it is submitted that

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claims 6-7 and 20 recite additional elements not taught or suggested by the cited references. Claim 6 recites use of a gel as an actuating fluid. Claim 7 recites a bladder and a fluid that are a unitary body of semisolid material. Claim 20 recites two bladders working in combination to simulate a heart. Neither *Poirier* nor *Gealow* disclose or suggest such elements. Because claims 5-7, 11 and 20 recite elements not disclosed or suggested by the cited references, a *prima facie* case of obviousness has not been made, and the rejection must be withdrawn.

New claims 32-42 have been presented for consideration and are believed allowable. New claims 32-34 represent original claims 16-18 re-written in independent form. These original claims 16-18 were objected to as being dependent on a rejected claim, but were otherwise indicated to be allowable. New claims 32-34 are therefore allowable.

New claim 35 represents original claim 23 rewritten in independent form. Additionally, new claim 35 includes language to overcome the §112 rejection of original claim 21 from which claim 23 depended. Claim 24 has been amended to depend from claim 35. Because original claim 23-24 were objected to but otherwise indicated to be allowable, new claim 35 and amended claim 24 are believed to be allowable.

New claim 36 represents original claim 27 rewritten in independent form. Original claim 27 was objected to but indicated as being allowable if re-written in independent form.

New claim 37 has also been presented for consideration. New claim 37 is believed allowable as it includes elements not disclosed or suggested by the prior art. Claim 37 is directed to a blood pump having an elastic bladder as well as means for decreasing a bladder driving pressure to below atmospheric to cause the

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bladder to elastically stretch to store energy and increase surface area. Claim 37 further recites the bladder being elastically contracted when exposed to a high pressure that is at or below arterial pressure. This structure is not taught or suggested by the references. Instead, these references teach a bladder that is in an *expanded* shape when its interior is exposed to arterial pressure, and that requires *positive* pressure (above arterial) to pump a fluid.

As described in the present specification, use of negative pressure (e.g., below atmospheric) to drive pumping, as is recited by new claim 37, is advantageous over the prior art for numerous reasons. For example, the absence of a driving pressure above arterial pressure reduces or eliminates the chance of actuating fluid entering the blood stream in the event of a bladder rupture. See specification, p. 5, line 30 - p. 6, line 2.

New claim 38 recites a method for reducing the formation of blood clots during blood pumping, and recites stretching and contracting a bladder to change the bladder surface area. As described in the specification, it is believed that this changing surface area is operative to reduce blood clot formation on the interior bladder surface. See, e.g., specification, p. 5, lines 19-22. The references do not address this problem or solution.

New claim 39 depends from new claim 38, and recites use of pressure below atmospheric. As discussed herein above, the cited references do not disclose this step. For these reasons, new claims 38 and 39 are allowable.

New claim 40 depends from claim 2 and recites that the means for expanding and contracting the bladder are operative to vary the pressure around the bladder between a high of about atmospheric and a low below atmospheric.

As discussed herein above, the cited references do not disclose such a means. Claim 40 is therefore allowable.

New claim 41 depends from claim 1 and recites a mechanical drive for causing the bladder to expand and contract. Support for this claim can be found, for example, at page 5, line 2 of the specification. New claim 41 is allowable for the same reasons as claim 1 from which it depends is.

New claim 42 depends from claim 1 and recites a bladder made of a plurality of different materials. Support for this recitation can be found on page 7, line 8 of the specification. No prior art reference discloses or suggests this feature, with the result that claim 42 is allowable.

SUPPLEMENTAL IDS

Applicant has also transmitted herewith a First Supplemental Information Disclosure Statement disclosing a newly discovered reference. This reference was first obtained by Applicant's Counsel within the last 3 months. Applicant requests that the Examiner consider the cited reference.

CONCLUSION

The September 12, 2002 Office Action indicated that several claims contained allowable subject matter, but were objected to. These claims have been re-written to overcome the objections, and should be allowed.

The claims subject to rejection over the *Poirier* and *Gealow* references have been amended to clarify the invention, and are respectfully submitted to be allowable over the cited references.

Applicant's undersigned attorney believes that a telephone interview may be useful to facilitate an effective examination of the remaining claims, and respectfully requests to be contacted by telephone at the Examiner's early convenience.

Respectfully submitted,

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"Version with Markings to Show Changes Made"

In the Specification:

Please replace the paragraph beginning on page 4, line 8 with the following:

It is also an object of the invention to prevent intrusion of foreign matter into the bloodstream, and especially to prevent air embolisms of the driving fluid or other fluids as a result of a pump failure.

Please replace the paragraph beginning on page 14, line 21 with the following:

Due to the smooth internal configuration or shape of the bladder 12 and the manner in which blood is "milked" into and through the bladder, as depicted in Figs. 1A-1G, there are no areas within the path of blood flow that can become stagnant, diminishing the potential for damage to blood cells caused by undue turbulence and also diminishing clot formation.

In the Claims:

Cancel claims 16-18, 23, 25, 27, and 29-30 without prejudice.

Amend claims 1, 7, 14, 19, 21, 24 and 26, and add new claims 32 - 42 as follows:

1. (AMENDED) A fluid pump comprising:

a an elastic bladder, at least a portion of the interior surface area of said bladder being changeable between a contracted state have a first surface area and an expanded state having a second surface area that is substantially greater than said first surface area, said bladder having a fluid inlet and a fluid outlet;

means for alternately expanding and contracting the said bladder to change the interior surface area and volume of said bladder; and

means for causing substantially one-way fluid flow through said bladder.

7. (AMENDED) A fluid pump as in claim 2, wherein said bladder and said actuating fluid are a unitary body of semisolid material, the surface of said semisolid material functioning as said bladder interior surface.

14. (AMENDED) A fluid pump as in claim 1, wherein said bladder inlet and outlet are configured for attachment to a blood circulatory system, and wherein said fluid is blood.

19. (AMENDED) A fluid pump as in claim 1 for use as a ventricular assist device for a heart, wherein said outlet from said bladder is ~~connected to~~ configured for connection to the aorta of the heart.

21. (AMENDED) A blood pump comprising:

a housing;

an extensible and contractible bladder in said housing, ~~defining~~ defined between said housing and said bladder for receiving a bladder driving fluid, said bladder having an inlet and an outlet;

a check valve to at least one of said bladder inlet and outlet; and

means for altering the pressure of the driving fluid to alternately expand and contract the interior surface area and volume of said bladder in a pumping cycle, said pressure altering means operable to maintain the pressure between a high pressure and a low pressure, said low pressure being below atmospheric pressure, most of said interior

surface area of said bladder adapted to elastically expand in response to said low pressure and contract in response to said high pressure with each said pumping cycle.

24. (AMENDED) A blood pump as in claim 24 ~~35~~, further comprising at least one extensible strut spanning the interior of said bladder.

26. (AMENDED) A method of pumping a fluid, comprising the steps of:
providing an extensible and contractible bladder having an inlet and an outlet;

connecting the inlet and outlet of the bladder to a fluid circulation system;
expanding the interior surface area and volume of said bladder to draw fluid in through said inlet;

storing elastic energy in said bladder as said bladder is expanded;

closing said inlet;

recoiling said bladder to release said elastic energy; and

contracting the interior surface area and volume of said bladder to expel fluid through said outlet, said release of elastic energy contributing to said contracting step.

32. (NEW) A fluid pump comprising:

a bladder, at least a portion of the interior surface area of said bladder being changeable, said bladder having a fluid inlet and a fluid outlet, said bladder having thickness variations for controlling the expansion and contraction of said bladder;

means for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder; and

means for causing substantially one-way fluid flow through said bladder.

33. (NEW) A fluid pump comprising:

a bladder, at least a portion of the interior surface area of said bladder being changeable, said bladder having a fluid inlet and a fluid outlet;

means for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder;

means for causing substantially one-way fluid flow through said bladder;

and

at least one extensible strut spanning the interior of said bladder for controlling its expansion and contraction.

34. (NEW) A fluid pump comprising:

a bladder, at least a portion of the interior surface area of said bladder being changeable, said bladder having a fluid inlet and a fluid outlet;

means for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder;

means for causing substantially one-way fluid flow through said bladder;

and

one or more bands on said bladder for controlling its expansion and contraction.

35. (NEW) A blood pump comprising:

a housing;

an extensible and contractible bladder in said housing, a space defined between said housing and said bladder for receiving a bladder driving fluid, said bladder having an inlet and an outlet;

a check valve to at least one of said bladder inlet and outlet;

means for altering the pressure of the driving fluid to alternately expand and contract the interior surface area and volume of said bladder to define a pumping cycle, most of said interior surface area of said bladder adapted to expand and contract with each said pumping cycle; and

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a fluid pressure regulator in said space to selectively control the rate of expansion or contraction of selected areas of said bladder.

36. (NEW) A method of pumping a fluid, comprising the steps of:
providing an extensible and contractible bladder having an inlet and an outlet;
connecting the inlet and outlet of said bladder to a fluid circulation system;
expanding the interior surface area and volume of said bladder to draw fluid in through said inlet, said expanding step comprising initially expanding a portion of said bladder adjacent said inlet and gradually expanding the remaining portions of said bladder from said inlet towards said outlet;
closing said inlet; and
contracting the interior surface area and volume of said bladder to expel fluid through said outlet.

37. (NEW) A blood pump comprising:
a housing;
an elastic bladder contained within said housing having an interior volume containing blood at arterial pressure;
at least one check valve in communication with said bladder for causing substantially one-way fluid flow through said bladder;
a space defined between said bladder and said housing;
a driving fluid in said space; and
means in communication with said space and for, alternately, decreasing the pressure of said driving fluid to a low pressure that is below atmospheric pressure, said elastic bladder responding to said decreasing pressure by elastically stretching to store elastic energy in said bladder, to increase bladder surface area and volume and to draw blood into said bladder, and increasing the pressure of said driving fluid to a high pressure that is less than or equal to arterial pressure, said elastic bladder responding to

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said increasing pressure by elastically contracting to release elastic energy from said bladder, to decrease bladder surface area and volume and to pump blood from said bladder.

38. (NEW) A method for reducing the formation of blood clots during blood pumping, the method comprising the steps of:

providing a blood pump having an elastic bladder having an interior and an interior surface area; and

changing said interior surface area by alternately elastically stretching said bladder and elastically contracting said bladder, said changing surface area operative to reduce the formation of blood clots on said interior surface area.

39. (NEW) A method for reducing the formation of blood clots during blood pumping as defined by claim 38, wherein said elastic bladder is enclosed in a housing, a space defined between said bladder and said housing, and wherein the step of stretching and contracting said bladder includes elastically stretching said bladder by decreasing pressure in said space to below atmospheric, and contracting said bladder by increasing the pressure in said space.

40. (NEW) A fluid pump as defined by claim 2, wherein said means for alternately expanding and contracting said bladder are operative to vary the pressure surrounding said bladder between a high of about atmospheric and a low of below atmospheric, said bladder being expanded when said pressure is at said low pressure and contracted when said pressure is at said high pressure.

41. (NEW) A fluid pump as defined by claim 1 wherein said means for alternately expanding and contracting said bladder comprises a mechanical drive.

42. (NEW) A fluid pump as defined by claim 1 wherein said bladder is comprised of a plurality of different materials.

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